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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/825,127 | 04/16/2004 | Naoyuki Fukuchi | 251865US0CONT | 7991 |
| 22850 | 7590 | 11/23/2007 | | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER GABEL, GAILENE | |
| | | | ART UNIT 1641 | PAPER NUMBER |
| | | | NOTIFICATION DATE 11/23/2007 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/825,127 | Applicant(s) FUKUCHI ET AL. | |
| | Examiner Gailene R. Gabel | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 21-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 21-31 and 35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response, filed August 23, 2007 is acknowledged and has been entered. Claims 31 and 35 have been amended. Claims 32-34 have cancelled. Claims 21-30 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 21-31 and 35 are pending. Claims 31 and 35 are under examination.

Withdrawn Rejections

2. The rejections of claims 32-34 are now moot in light of Applicant's cancellation of the claims.

3. In light of Applicant's amendment, the rejection of claims 31 and 35 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

4. In light of Applicant's amendment, the rejections of claims 31 and 35 under 35 U.S.C. 103(a) as being unpatentable over Ruggeri et al. (WO 93/16712) in view of Simonet et al. (US 6,790,823), and also further in view of Foster et al. (US Patent 4,444,879) are hereby, withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez et al. (Cloning of the alpha chain of human platelet glycoprotein Ib: a transmembrane. Proc. Natl. Acad. Sci. USA 84: 5615-5619 (December 28, 1987)) in light of Ruggeri et al. (WO 93/16712), in view of Simonet et al. (US 6,790,823).

Lopez et al. teach a partial protein which consists of amino acid residues 1-319 of human glycoprotein Ib chain. According to Lopez et al., the partial protein contains therein the von Willebrand factor binding site of glycoprotein Iba chain (see Abstract, page 5615, first and second column, and Figure 2).

Ruggeri et al. disclose antithrombotic polypeptides based upon partial proteins (fragments) of glycoprotein Iba (GPIba). In as far as the actual binding site for vWF, Ruggeri et al. specifically provide that the actual binding site for vWF on GPIb-IX receptor is localized within and consists of the region of GPIba chain comprising amino acid 1-293 residues of the GPIba chain. The polypeptides are modified and patterned on fragments of GPIba that comprise all or part of the binding domain of GPIba for von Willebrand Factor (vWF). See page 9, lines 3-24; page 12, lines 24-31; page 13, lines 15-39; and page 16, lines 15-19.

Lopez et al. and Ruggeri et al. differ from the instant invention in failing to teach fusing the partial protein to an Fc region of immunoglobulin molecule fused at its amino terminus.

Simonet et al. disclose a chimeric protein comprising a fusion of a polypeptide with an Fc region of human immunoglobulin G (IgG). Simonet et al. specifically teaches that fusion to the Fc region may occur between the amino terminus of an Fc region and the carboxy terminus of the polypeptide. See column 5, lines 50-62 and column 4, lines 25-50.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate an Fc region of human IgG in the amino terminus of the Fc region as taught by Simonet into the vWF binding site of the GPIIb α chain which consists of a partial protein as taught by Lopez in light of Ruggeri to form a chimeric protein because Simonet suggested fusion of an Fc region of human IgG into a modified polypeptide such as that taught by Ruggeri which comprises of a modified polypeptide in the form of a partial protein which consists of the vWF binding site of the GPIIb α chain. Additionally, generation of chimeric or fusion proteins by virtue of fusion of protein fragments with specific Ig fragments appears to be conventional and well-known practice in pharmaceutical medicine for treatment of different types of diseases.

NOTE: Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

5. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez et al. (Proc. Natl. Acad. Sci. USA 84: 5615-5619 (December 28, 1987)) in view of Simonet et al. (US 6,790,823) and in further view of Foster et al. (US Patent 4,444,879).

Lopez et al., Ruggeri et al., and Simonet et al. are discussed supra. Lopez et al., Ruggeri, and Simonet et al. differ from the instant invention in failing to teach incorporating the vWF and the chimeric protein into a kit format.

Foster et al. teach incorporating reagents, proteins, antibodies, antigens, and labels into a kit format. See column 15.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the vWF and chimeric protein taught by Lopez in light of Ruggeri as modified by Simonet, into a kit arrangement as taught by Foster because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

NOTE: Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.\

Response to Arguments

6. Applicant's arguments with respect to claims 31 and 35 have been considered but are moot in view of the new grounds of rejection.

7. No claims are allowed.

8. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

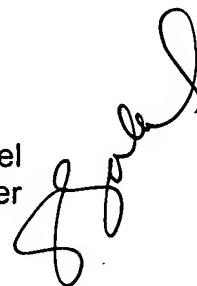
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Primary Examiner
Art Unit 1641



November 13, 2007